UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,345	05/09/2005	Els Beirnaert	A0848.70007US00	4825

23628 7590 06/10/2009

WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
06/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,345	BEIRNAERT, ELS	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16-21,26,28,30,32,34,36,38-41 and 44-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13, 16-21, 26, 28, 30, 32, 34, 36, 38-41 and 44-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment to the claims filed May 9, 2005 is acknowledged.

Claims 14, 15, 22-25, 27, 29, 31, 33, 35, 37, 42-43 and 49 have been canceled.

Claims 1-13, 16-21, 26, 28, 30, 32, 34, 36, 38-41 and 44-48 are pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

   This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

   Group I, claim(s) 1-11, 13, 16 and 40, drawn to an anti-IFN-gamma polypeptide comprising at least one anti-IFN-gamma single domain antibody and pharmaceutical compositions thereof.

   Group II, claim(s) 12, drawn to a composition comprising an anti-IFN-gamma polypeptide according to claim 1 together with at least one single domain antibody from the group consisting of anti-TNF-alpha single domain antibody, anti-TNF-alpha receptor single domain antibody and anti-IFN-gamma receptor single domain antibody, for simultaneous, separate or sequential administration to a subject.

   Group III, claim(s) 17, drawn to a nucleic acid encoding an anti-IFN-gamma polypeptide comprising at least one anti-IFN-gamma single domain antibody.

   Group IV, claim(s) 18 and 19, drawn to a method of identifying an agent that modulates the binding of an anti-IFN-gamma polypeptide to IFN-gamma and a method of identifying an agent that modulates IFN-gamma-mediated disorders through the binding of an anti-IFN-gamma polypeptide to IFN-gamma.

   Group V, claim(s) 20, drawn to a method of identifying an agent that modulates the binding of IFN-gamma to its receptor through the binding of an anti-IFN-gamma polypeptide to IFN-gamma

   Group VI, claim(s) 21, drawn to a kit for screening for agents that modulate IFN-gamma-mediated disorders comprising an anti-IFN-gamma polypeptide of claim 1 and IFN-gamma.

Group VII, claim(s) 26, 28, 30, 32, 34, 36, 38 and 39, drawn to methods of treatment where the IFN-gamma polypeptide of claim is administered to the intestine, upper respiratory tract/lung, beneath the tongue, or through the skin.

Group VIII, claim(s) 41, drawn to a method of diagnosis using the polypeptide of claim 1.

Group IX, claim(s) 44, drawn to a method purifying IFN-gamma using the polypeptide of claim 1.

Group X, claim(s) 45 drawn to a method for inhibiting the interaction between IFN-gamma and one or more IFN-gamma receptors, comprising contacting IFN-gamma with the anti-TNF-alpha polypeptide of claim 1.

Group XI, claim(s) 46-48 drawn to methods of making the polypeptide of claim 1.

3. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention of Group I, for example, lack unity of invention in view of Winter et al., US 20040219643, at page 3, paragraph [0025].

4. This application contains claims directed to more than one species of the generic invention.

   These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

   The species are as follows:

5. If applicant elects any Group where the claims recite the anti-IFN-gamma polypeptide comprising at least one anti-IFN-gamma single domain antibody of claim 1, applicant is required to elect if the anti-IFN-gamma polypeptide is:

   A. an anti-IFN-gamma-anti-serum protein polypeptide;
   B. an anti-IFN-gamma-anti-TNFα polypeptide;
   C. an anti-IFN-gamma-anti-TNFα receptor polypeptide;
   D. an anti-IFN-gamma-anti-IFN-gamma-receptor polypeptide;
   E. an anti-IFN-gamma-anti-IFN-gamma polypeptide; or
   F. an anti-IFN-gamma polypeptide comprising an additional single domain antibody having specificity other than those recited above or an anti-IFN-gamma polypeptide comprising something other than another single domain antibody.

   Moreover, if applicant elects option A above, applicant is further required to elect if the serum protein is serum albumin (A'), serum immunoglobulins (A''), thyroxine-binding protein (A''') , transferrin (A'''') or fibrinogen (A''''').

6. Should applicant elect Group I for examination, whichever species A(A')-A(A''''') or B, C, D, E or F is elected in part I above for examination, applicant is further required to elect from the following species:

a. If applicant's elected species A(A')-A(A''''') or B, C, D, E or F is to be specified by a particular SEQ ID NO:

OR

b. If applicant's elected species A(A')-A(A''''') or B, C, D, E or F is *NOT* to be specified by a particular SEQ ID NO:

Should applicant elect option (a.) above, applicant is required to elect a particular species of SEQ ID NO: for each antibody specificity recited in the claims, as appropriate.

For example, if applicant were to elect Group I, with the species of antibody being species E, and further to elect (a.) above, then applicant would be required to elect a particular sequence(s) for the elected species of antibody from claims 3 and 10 as desired. Moreover, applicant may chose to specify the sequence for only one or both of the IFN-γ antibodies. For example, applicant might elect SEQ ID NO: 1 as recited in claim 3, but generic sequence for the second IFN-gamma antibody, in which case claim 10 would be withdrawn as being drawn to a non-elected species of invention.

As another example, if applicant were to elect Group I, with the species of antibody being species B, and further to elect (a.) above, then applicant would be required to elect a particular sequence(s) for the elected species of antibody from claims 3 and 13 as desired. Moreover, applicant may chose to specify the sequence for only one or both of the specific antibodies. For example, if applicant may chose a specific sequence for the IFN-gamma antibody, SEQ ID NO: 1 as recited in claim 3 and a specific sequence for the anti-TNFα antibody, SEQ ID NO: 43 as recited in claim 13.

ADDITIONALLY, whichever species A(A')-A(A''''') or B, C, D, E or F is elected in part I above for examination, applicant is further required to elect if the at least one single domain antibody is humanized Camelidae OR Camelidae.

7. Should applicant elect Group VII for examination, applicant is required to elect one particular disease to be treated from among the diseases recited in claim 39, such as rheumatoid arthritis OR Crohn's disease. An election of "inflammation" as the disease will not be considered responsive because most of the other disease recited in claim 39 are species of inflammation.

Moreover, applicant is ***further required*** to elect the route of delivery, for example, under the tongue, OR into the upper respiratory tract/lung etc.

8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

   Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

   In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.
    If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
    Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information

about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachary Skelding/
Examiner, Art Unit 1644